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09/463,480	04/07/2000	MOHAN SINGH	13334	6365

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EXAMINER

KUBELIK, ANNE R

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/463,480	<b>Applicant(s)</b> SINGH ET AL.	
	<b>Examiner</b> Anne R. Kubelik	<b>Art Unit</b> 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 September 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 4,5 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4,5 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. §§ 119 and 120**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☒ All    b) ☐ Some \*    c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1638

### **DETAILED ACTION**

1. Claims 4-5 and 21 are pending.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Applicant elected Group I, claims 4-5 and 21 to the extent they read on a nucleic acid encoding LGC1 (nucleic acids of SEQ ID NO:3 or that encode SEQ ID NO:4) in a telephone conversation with Frank Digiglio on 21 February 2003 and as restated in the Office action mailed 6 March 2003. Because Applicant did not distinctly and specifically point out the supposed errors in the restriction requirement in replying to that Office action, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant did acknowledge the election of SEQ ID NO:3 on pg 5, paragraph 3, of the response filed 11 September 2003.

The restriction is thus made FINAL.

4. This application contains sequences SEQ ID NO:5-8 drawn to an invention nonelected with traverse as above. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

### ***Withdrawn Rejections***

5. The rejection of claims 4-5 and 21 under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had

Art Unit: 1638

possession of the claimed invention is withdrawn in light of Applicant's amendment of the claims.

6. The rejection of claims 4-5 and 21 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention is withdrawn in light of Applicant's amendment of the claims.

7. The rejection of claims 4-5 and 21 under 35 U.S.C. 102(b) as being clearly anticipated by Baszczynski et al (1997, US Patent 5,633,438) is withdrawn in light of Applicant's amendment of the claims.

8. The rejection of claims 4-5 and 21 under 35 U.S.C. 102(b) as being clearly anticipated by Tuttle et al (1995, US Patent 5,477,002) is withdrawn in light of Applicant's amendment of the claims.

#### ***Claim Rejections - 35 USC § 101***

9. Claims 4-5 and 21 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well-established utility. The rejection is repeated for the reasons of record as set forth in the Office action mailed 6 March 2003. Applicant's arguments filed 11 September 2003 have been fully considered but they are not persuasive.

Applicant urges that SEQ ID NO:3 has a specific utility of permitting specific genetic manipulation of the male germ line, including generating male sterile plants; it can serve as a target sequence for the introduction of a transgene via homologous recombination, marker

Art Unit: 1638

exchange mutagenesis or gene targeting and genes introduced by this manner would be expressed only in the male gametes (response pg 5-6).

This is not found persuasive because introduction of a transgene via homologous recombination, marker exchange mutagenesis or gene targeting is not possible in plants and is not taught in the instant specification. Thus, such a utility is not a well-established utility in plants.

Furthermore, such a utility is not taught in the instant specification. The only utilities for the coding sequence, independent of utilities recited for the promoter naturally associated with that coding sequence, are below:

Pg 12, lines 5-7, of the specification recites the utility:

Alternatively, the cytotoxic nucleic acid molecule is fused to the gene naturally operably linked to said promoter such that upon expression of said gene, the cytotoxic nucleic acid molecule inactivates, kills or otherwise renders substantially non-function a male gamete in said plant.

Making male sterile plants by fusing a toxin gene to a gene naturally operably linked to the LGC1 male-gamete specific promoter relies on the LGC1 promoter, which is not part of SEQ ID NO:3. Additionally, as any protein-encoding region can be used in a toxin fusion construct under control of a male-gamete specific promoter, such a use is not specific to SEQ ID NO:3.

Pg 12, lines 9-12, of the specification recites the utility:

In another embodiment, the male gamete specific promoter and/or gene is used to facilitate male gamete specific transposon tagging. This facilitates the product of pollen grains in a plant carrying a transposon tag. Offspring can then be screened for a range of phenotypes of interest and then, in turn, the transposon tagged plants used to clone particular genes.

Transposon tagging is only proposed for isolation of genes. Transposon tagging of SEQ ID NO:3 would result in isolation of SEQ ID NO:3. There is no utility for SEQ ID NO:3, as discussed above. Thus, such a utility is not specific.

Art Unit: 1638

It is apparent that extensive further research, not considered to be routine experimentation, would be required before one skilled in the art would know how to use the claimed invention. It has been established in the courts that a utility that requires or constitutes carrying out further research to identify or reasonably confirm a "real world" context of use is not a substantial utility:

***Claim Rejections - 35 USC § 112***

10. Claims 4-5 and 21 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 6 March 2003. Applicant's arguments filed 11 September 2003 have been fully considered but they are not persuasive.

Applicant arguments are summarized above. They are not found persuasive for the reasons above.

11. Claims 4-5 and 21 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 6 March 2003. Applicant's arguments filed 11 September 2003 have been fully considered but they are not persuasive.

Art Unit: 1638

Applicant urges that the claims have been amended to recite specific nucleotide and amino acid sequences (response pg 6-7).

This is not found persuasive because the specification does not teach a specific use of a nucleic acid of SEQ ID NO:3. As the function of the encoded protein is not disclosed, one of skill in the art would not know how to use it. As discussed above, it is apparent that extensive further research, not considered to be routine experimentation, would be required before one skilled in the art would know how to use the claimed invention.

### *Conclusion*

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service at (703) 308-0198.

Anne R. Kubelik, Ph.D.  
December 5, 2003

  
**ASHWIN D. MEHTA, PH.D.**  
**PATENT EXAMINER**